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(54) **MRI BIOPSY DEVICE**

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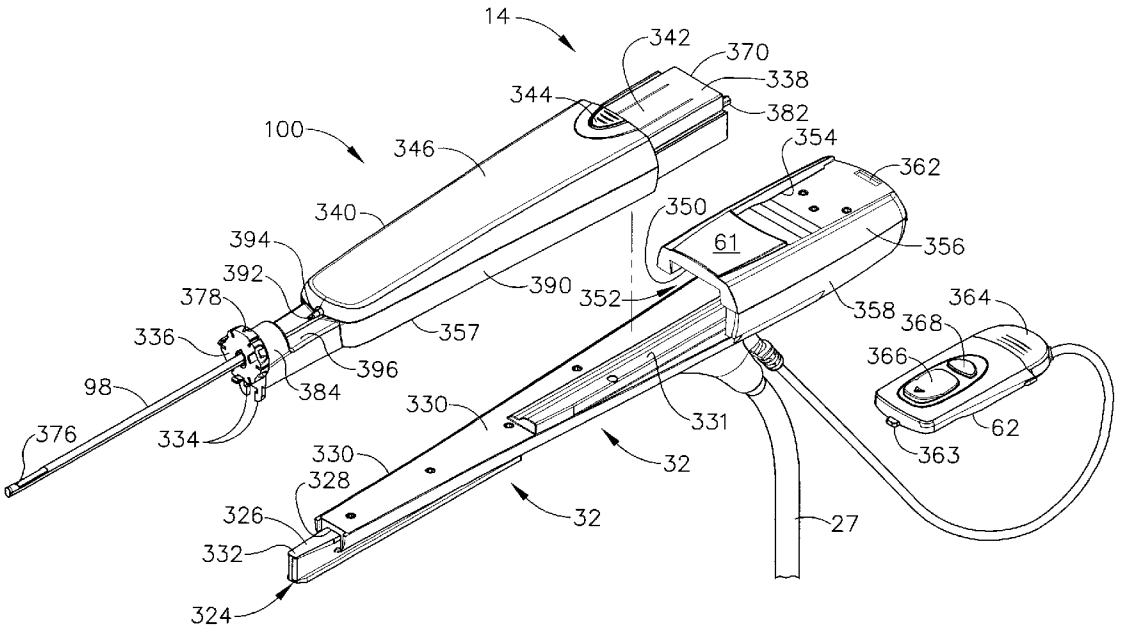
(57) **ABSTRACT**

A magnetic resonance imaging (MRI) compatible core biopsy system uses a biopsy device having intuitive graphical displays and a detachable remote keypad that advantageously allows convenient control even within the close confines afforded by a localization fixture installed within a breast coil that localizes a patient's breast and guides a probe of the biopsy device relative to the localized breast. A control module for interactive control and power generation are remotely positioned and communicate and transmit rotational mechanical energy via sheathed cable.



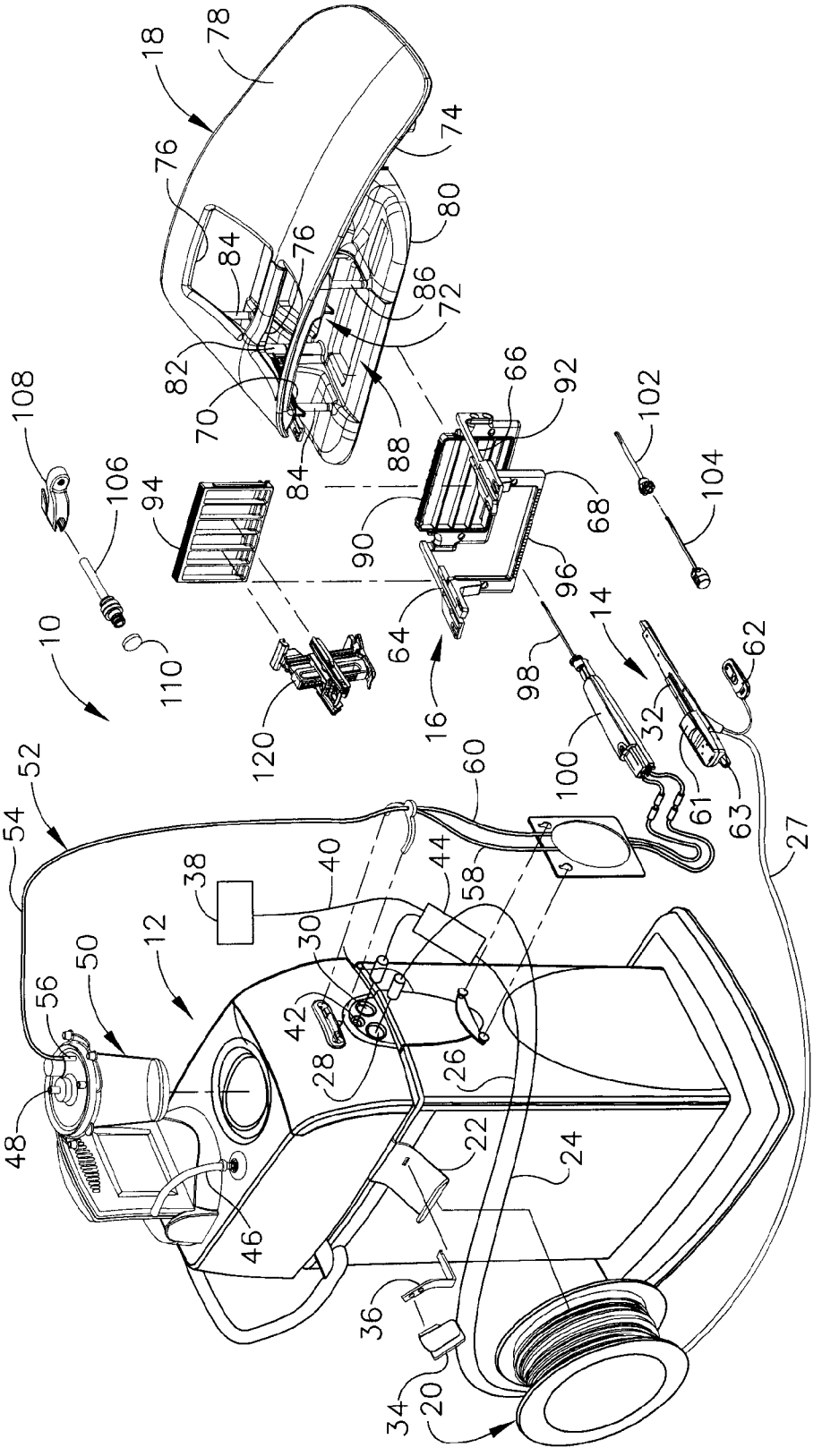

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FIG. 1

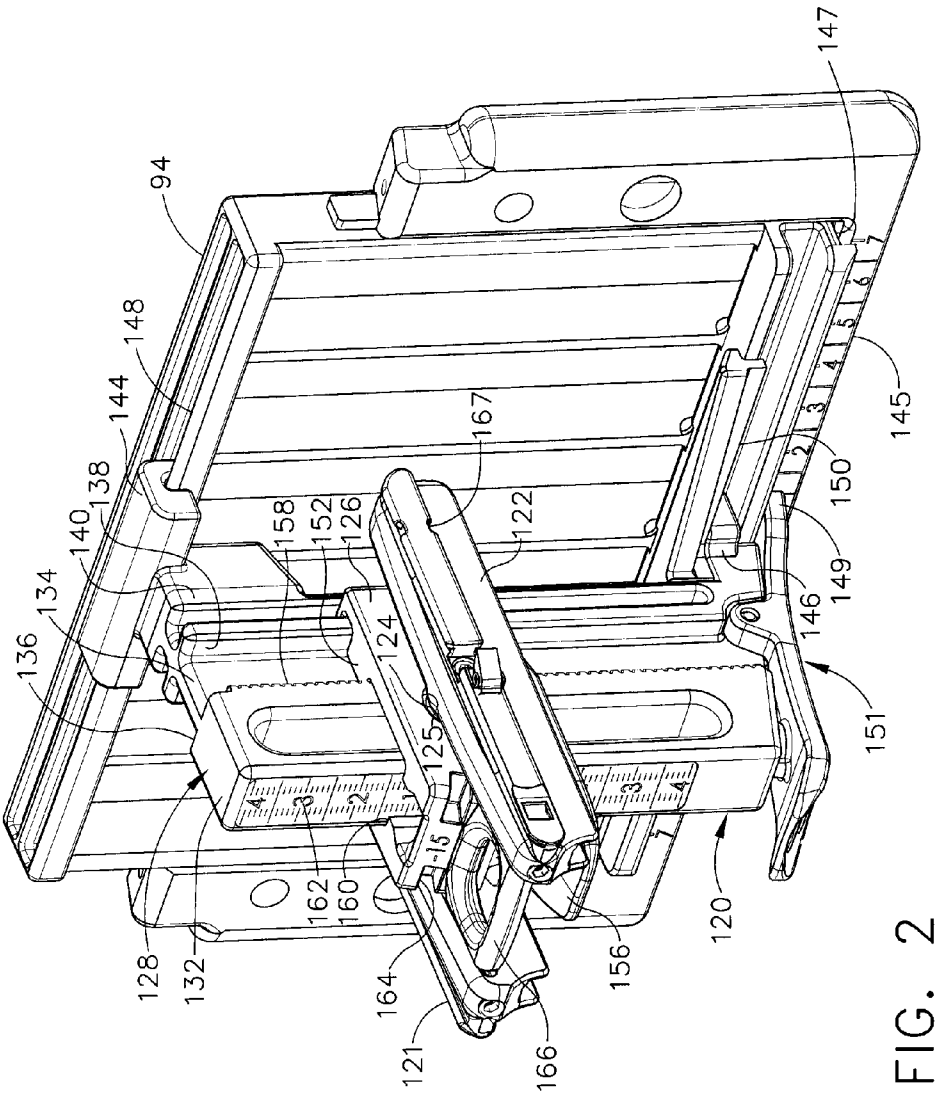
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FIG. 2

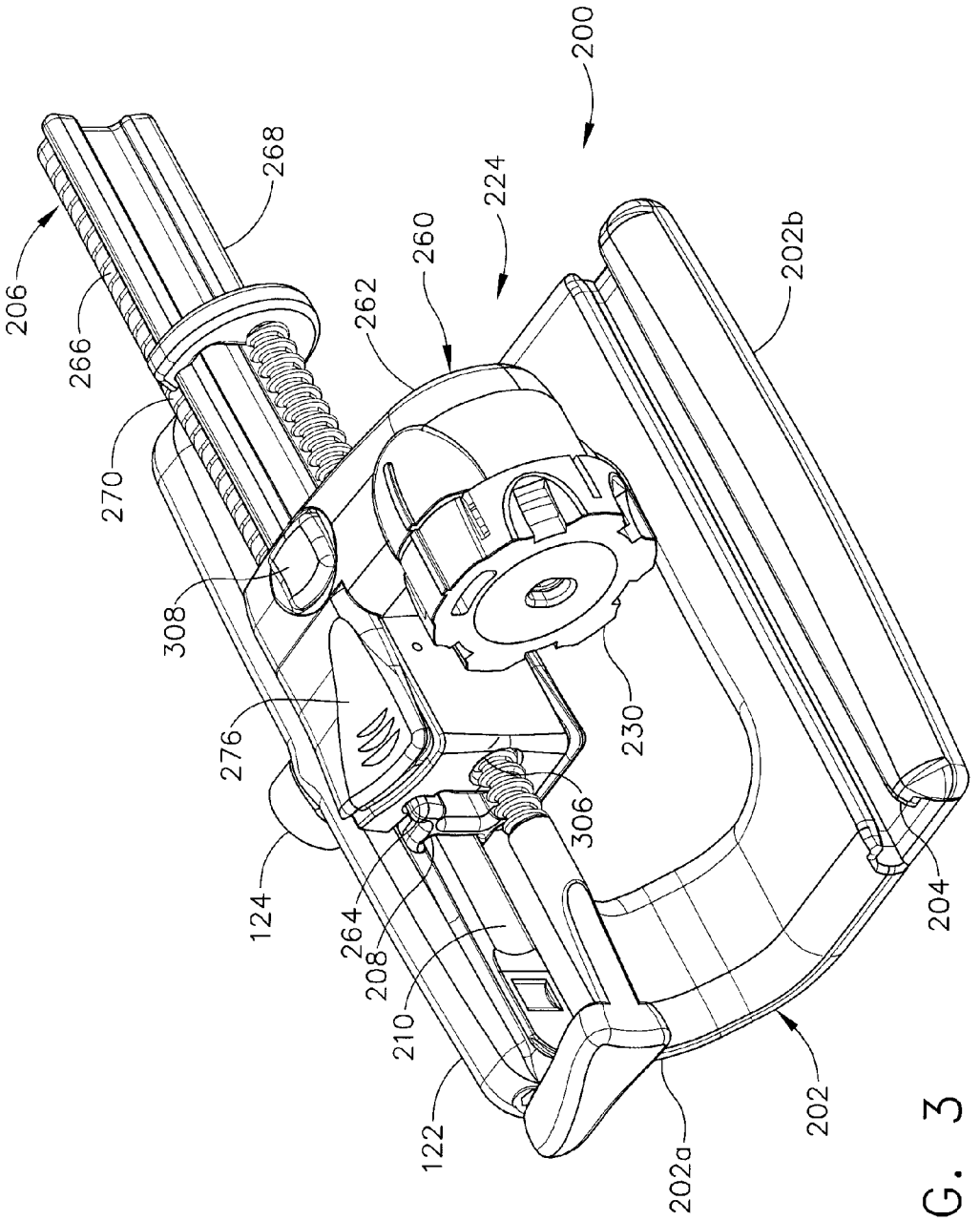
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FIG. 3

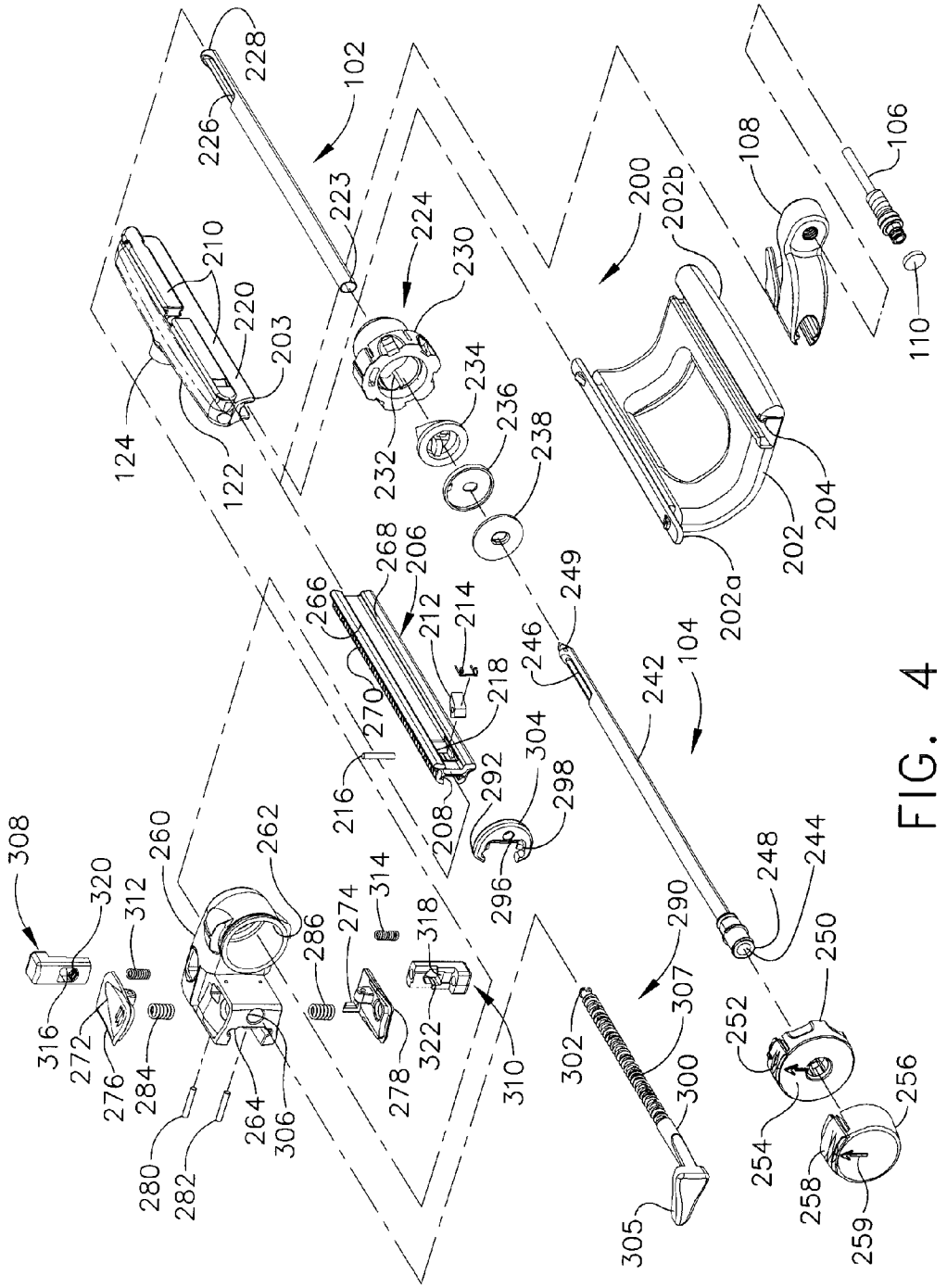
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FIG. 4

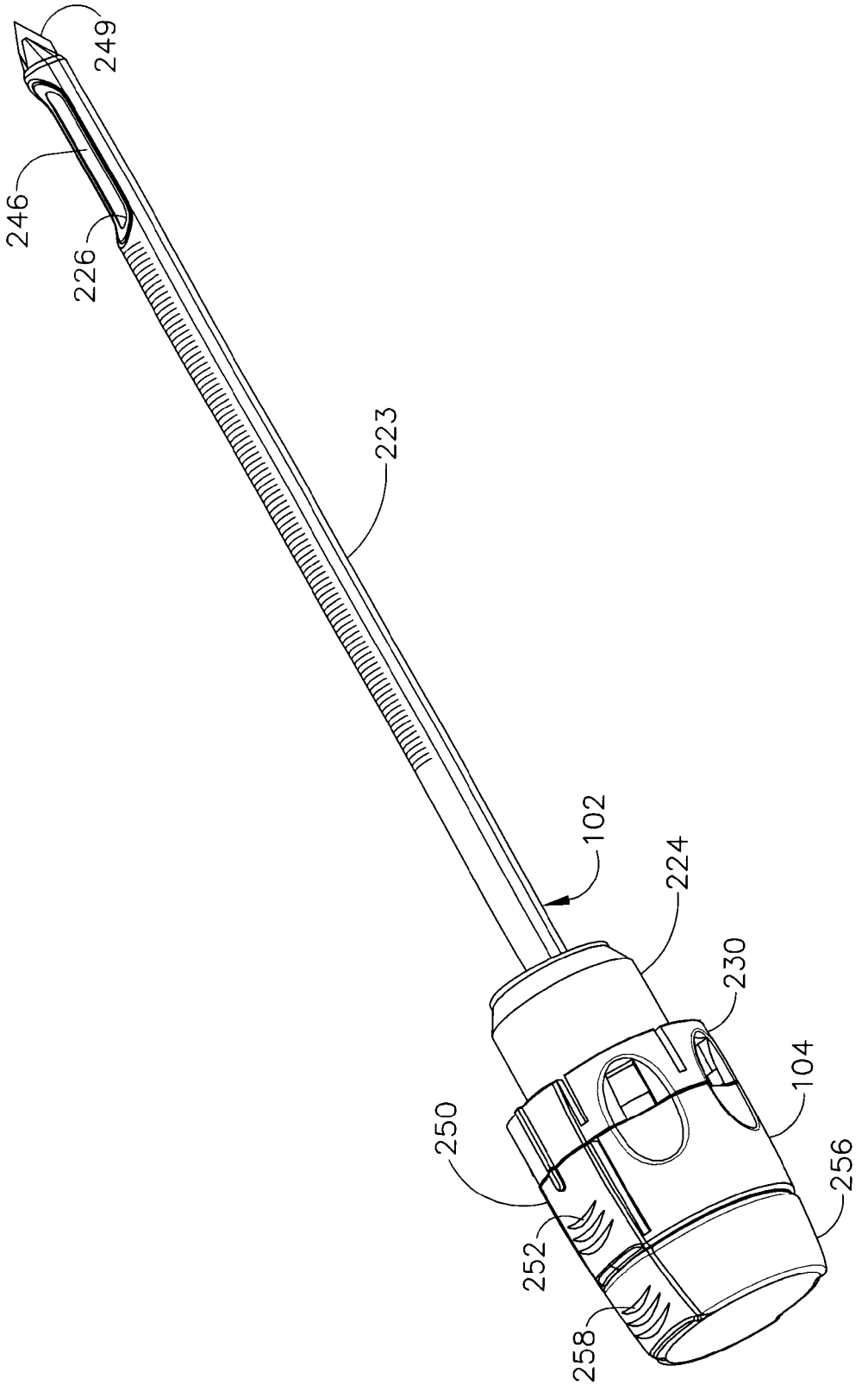

FIG. 5

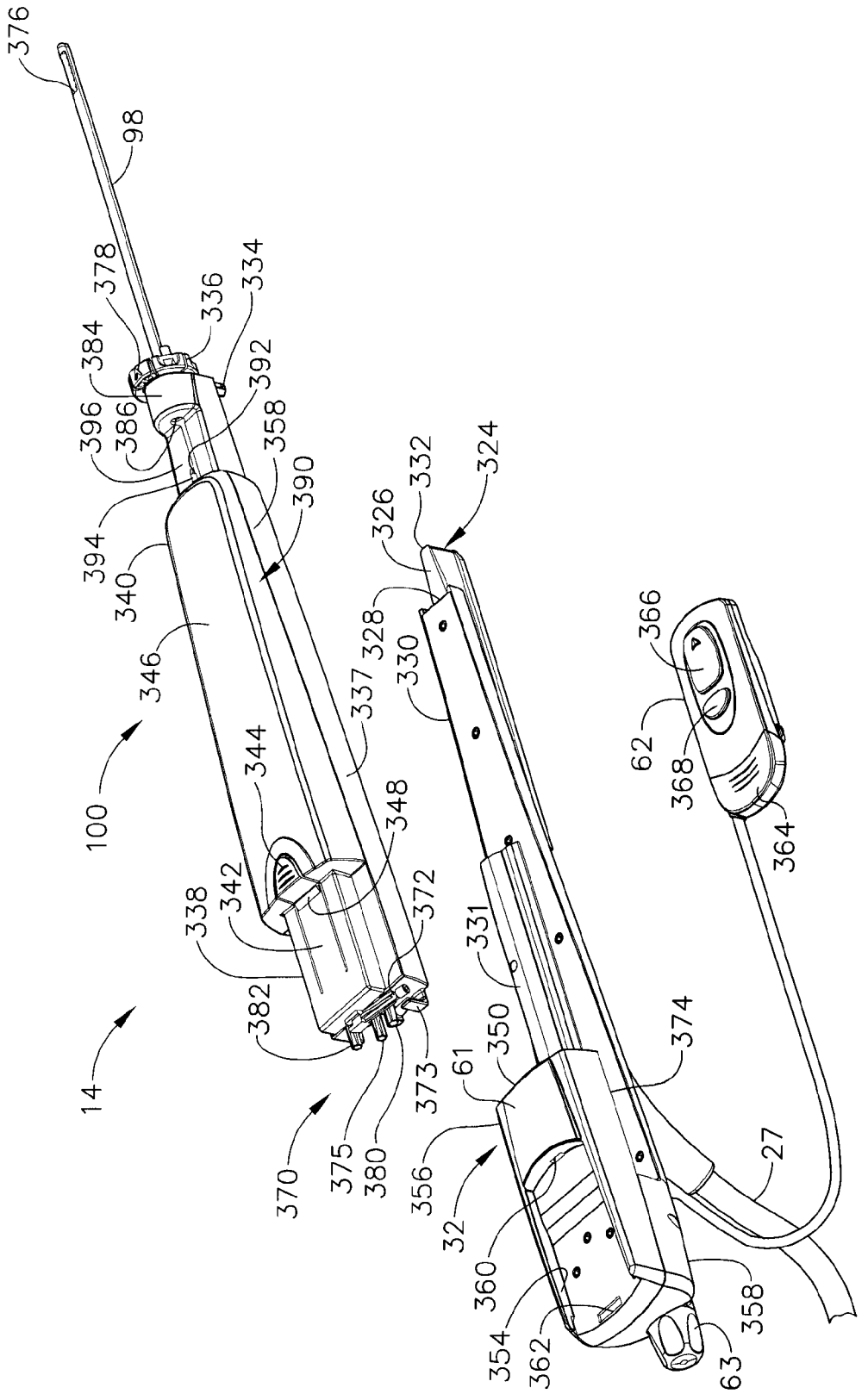
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FIG. 6

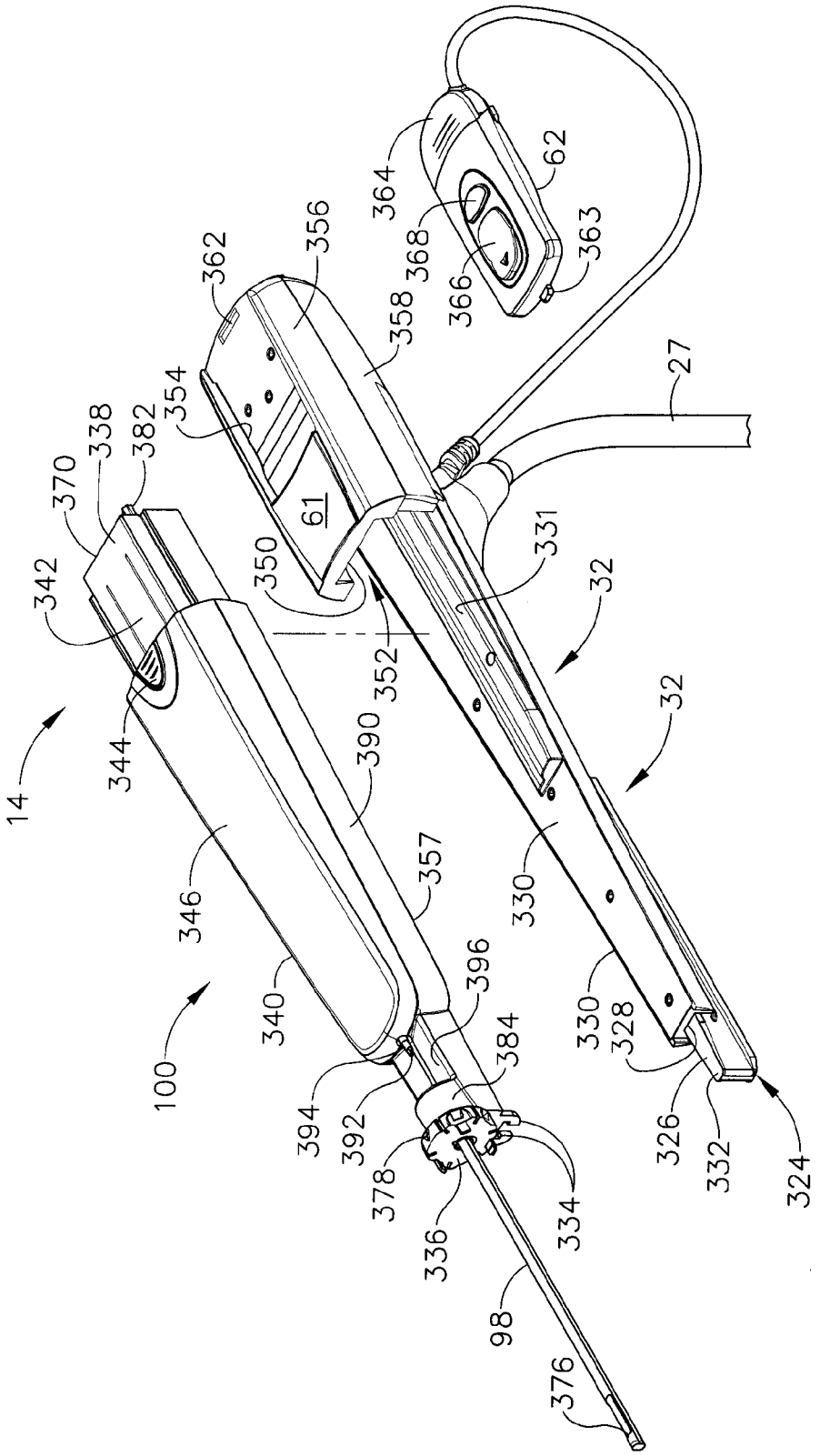
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FIG. 7

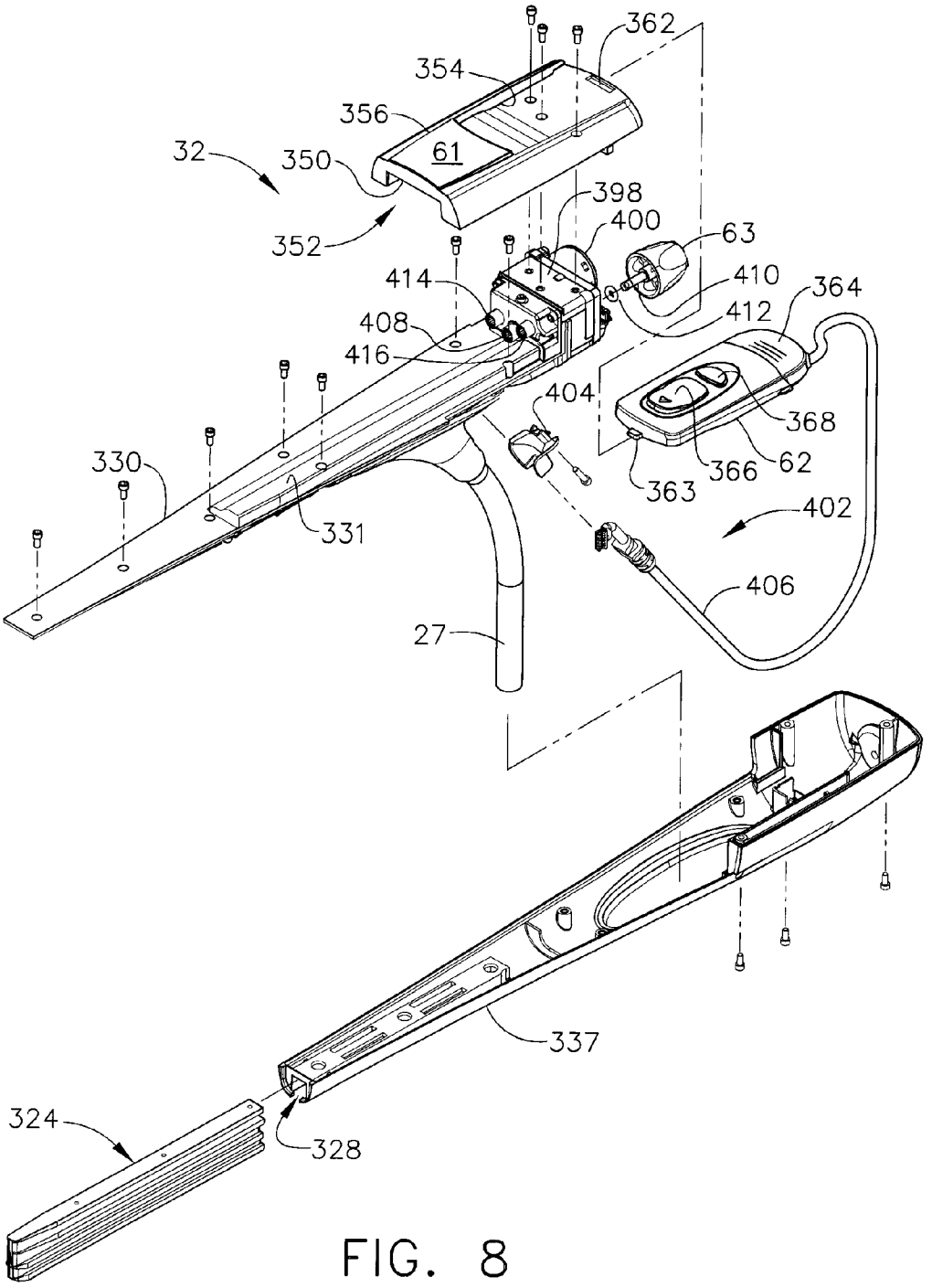
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FIG. 8

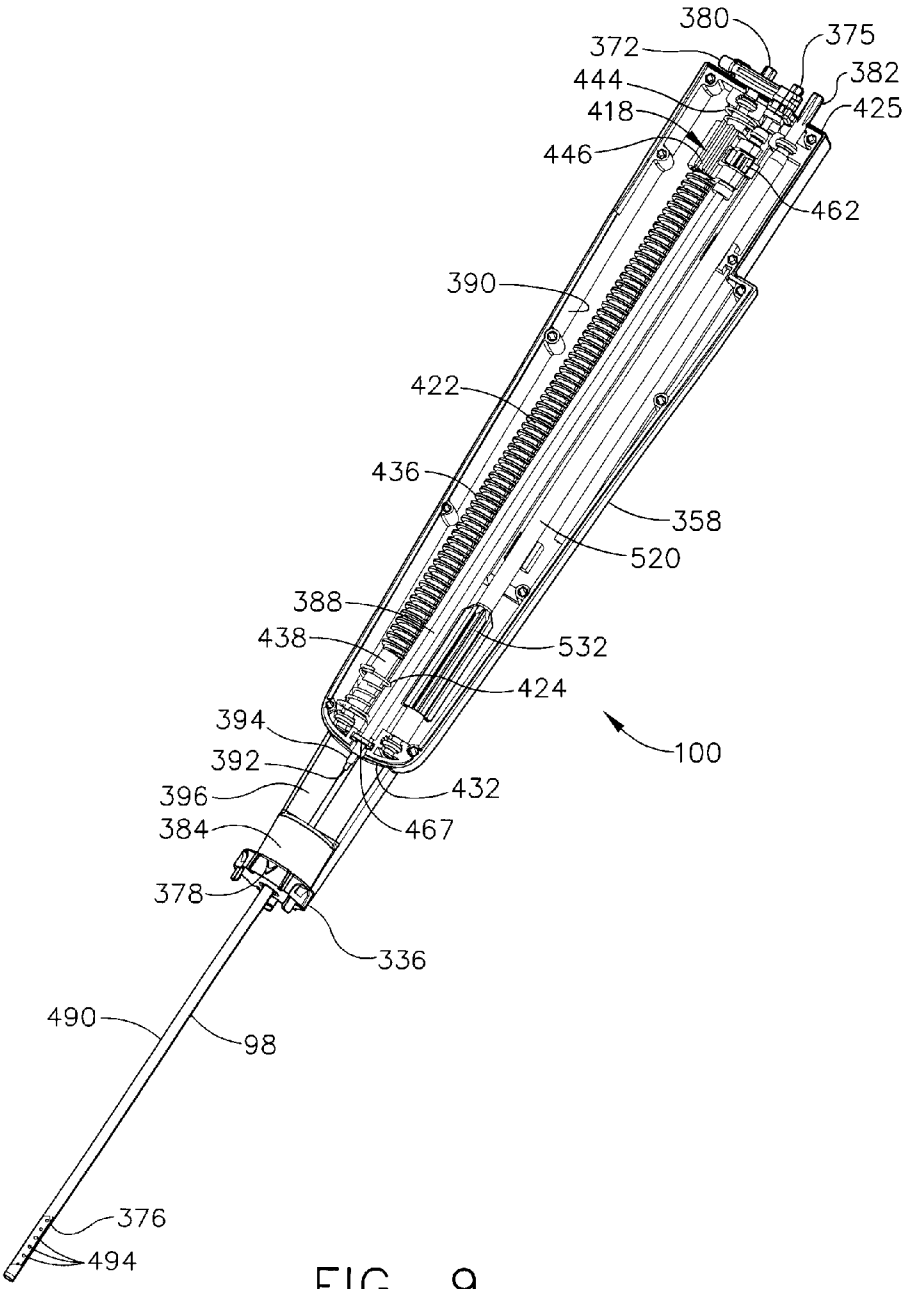
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FIG. 9

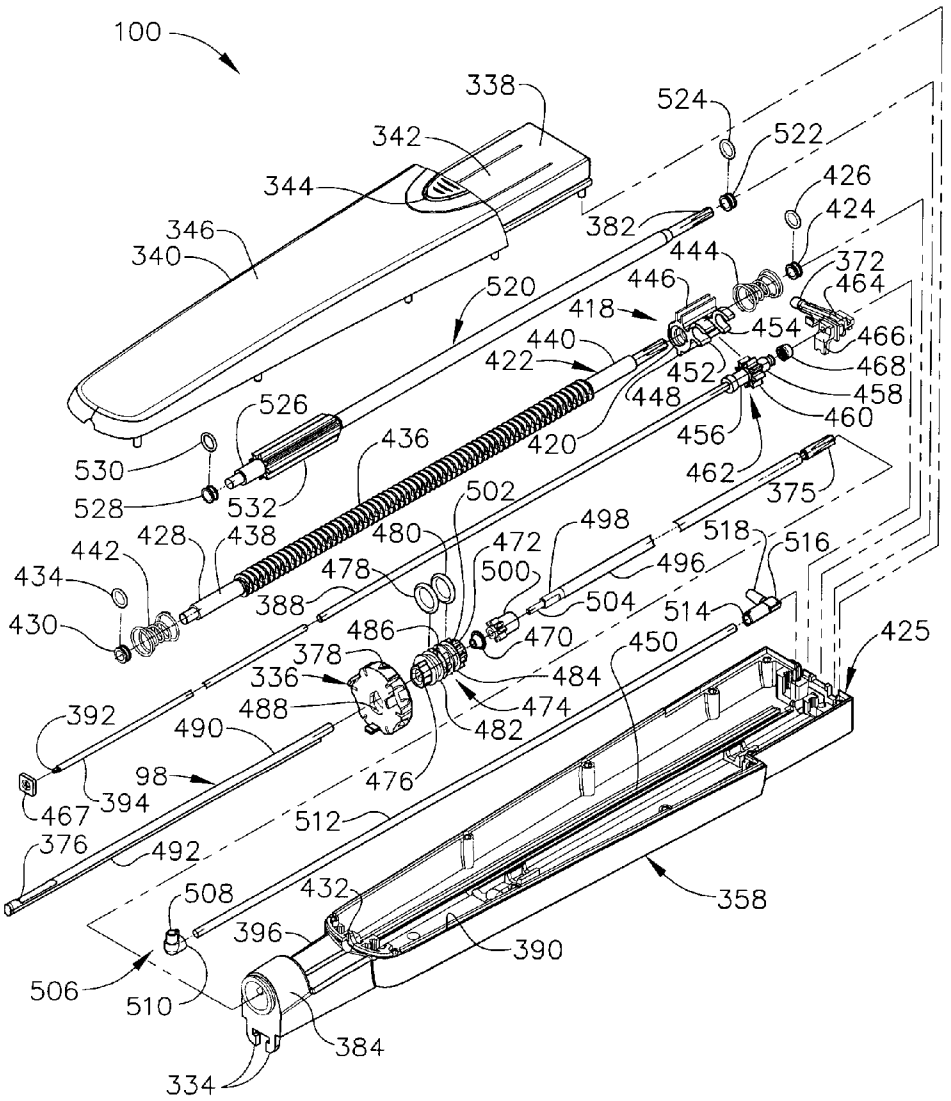
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FIG. 10

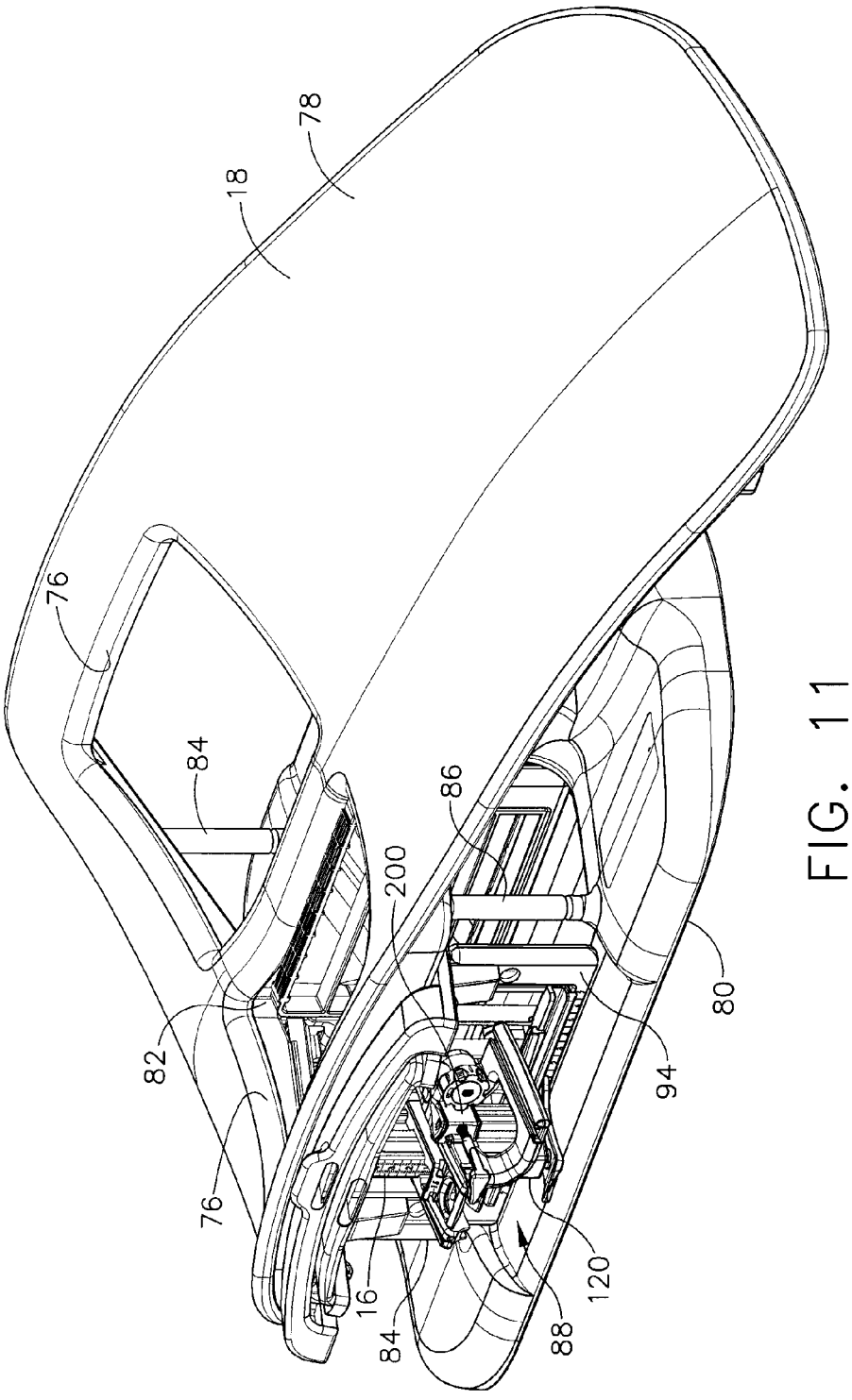

FIG. 11

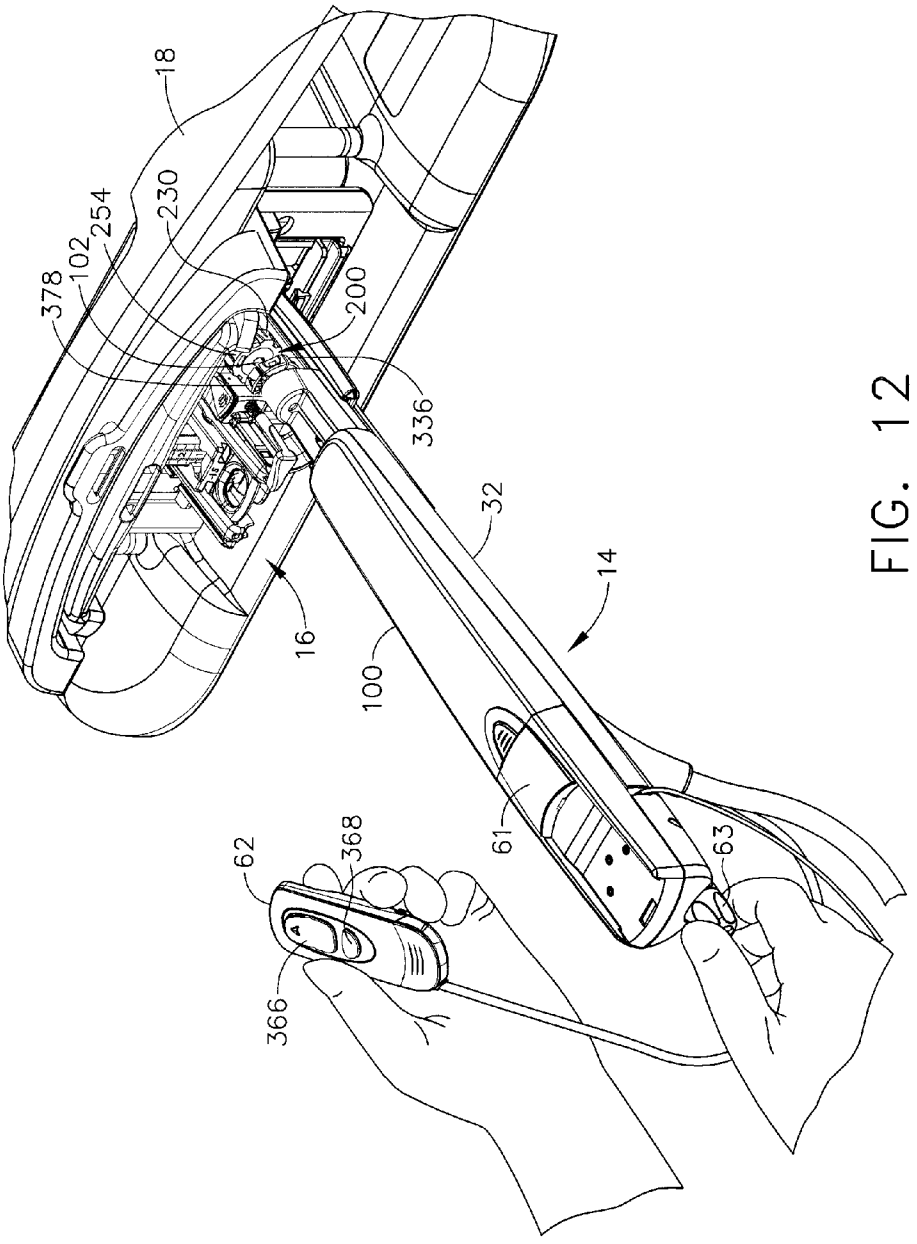

FIG. 12

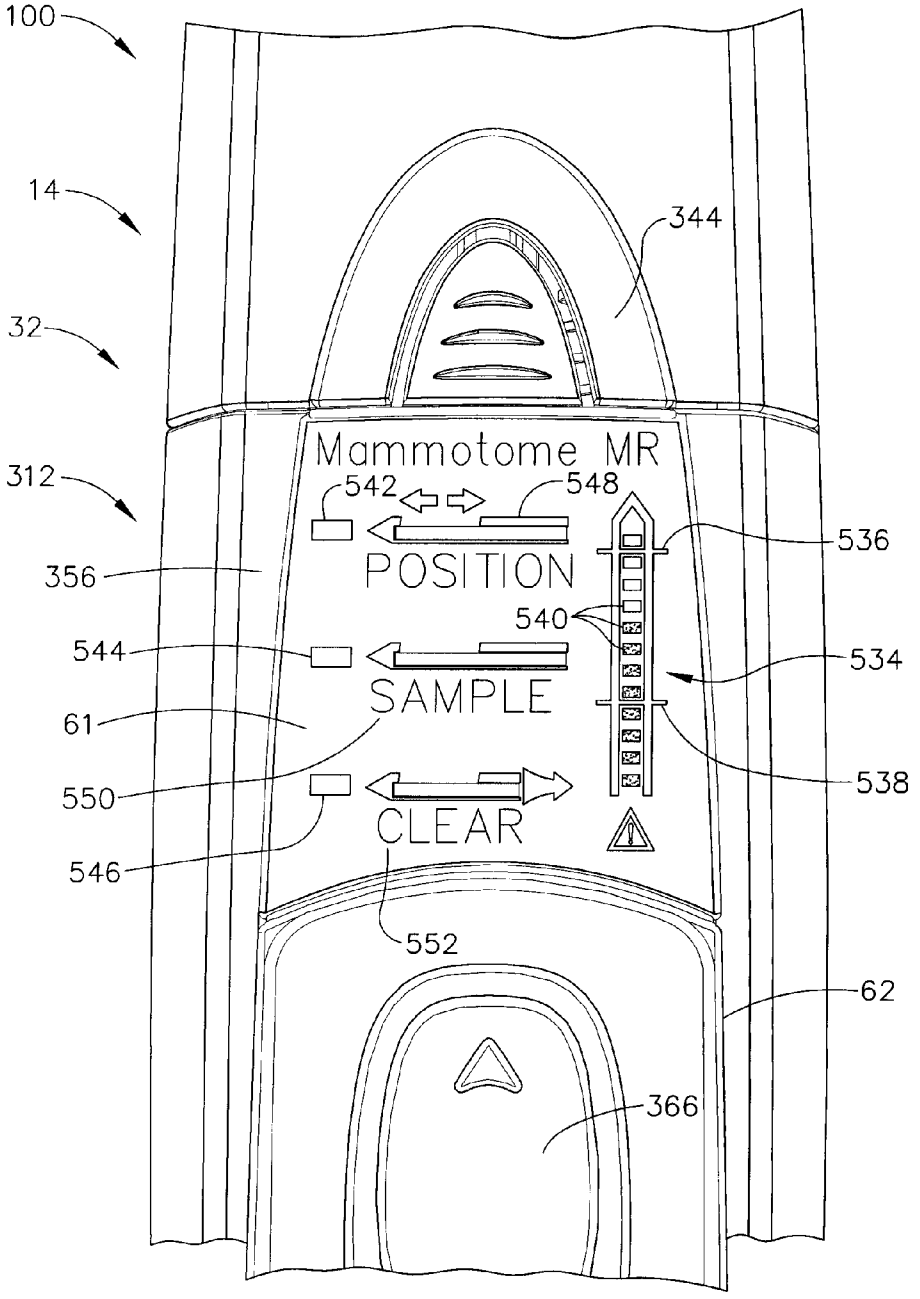
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FIG. 13

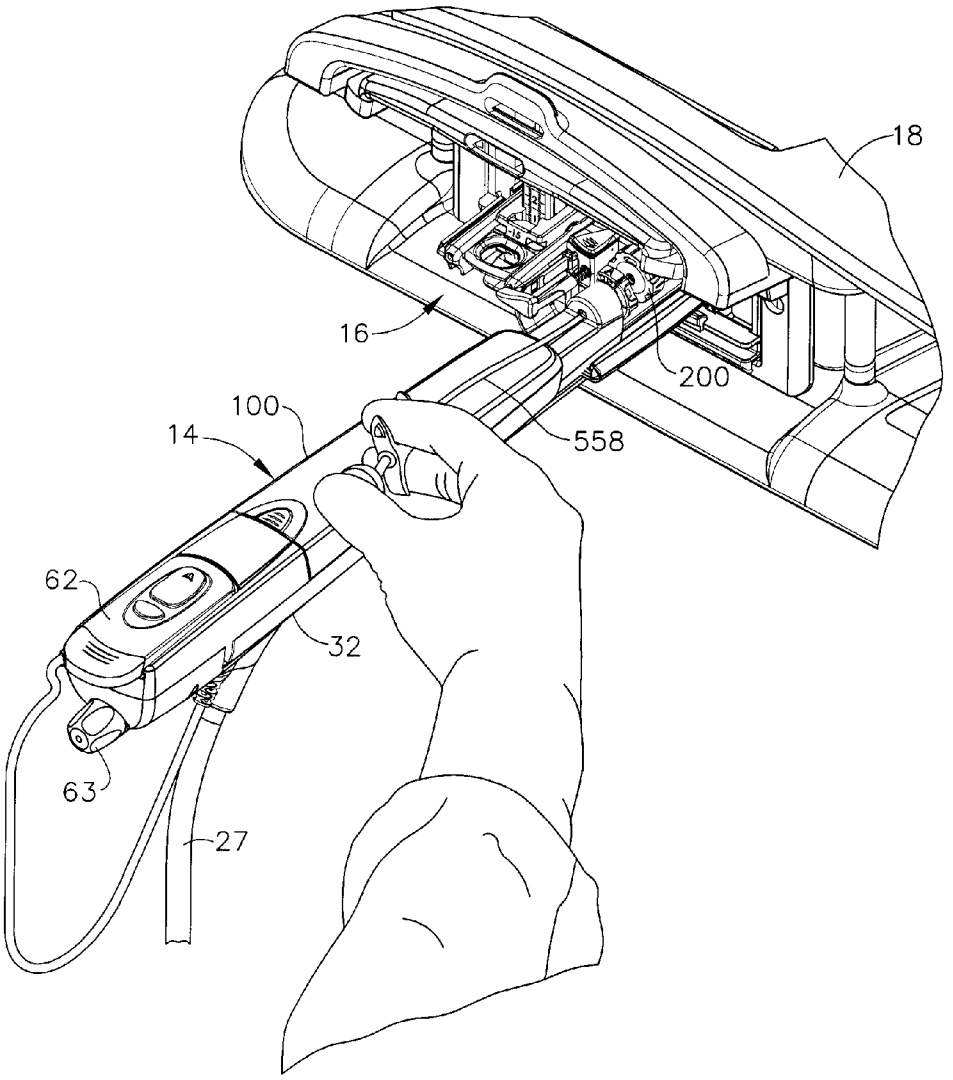

FIG. 14

MRI BIOPSY DEVICE

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation in part of U.S. patent application Ser. No. 11/103,959, "MRI BIOPSY DEVICE LOCALIZATION FIXTURE" to Hughes et al., filed on 12 Apr. 2005, the disclosure of which is hereby incorporated by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates, in general, to a method of imaging assisted tissue sampling and, more particularly, to an improved method for positioning a biopsy probe with respect to a magnetic resonance imaging (MRI) breast coil for acquiring subcutaneous biopsies and for removing lesions.

BACKGROUND OF THE INVENTION

[0003] Core biopsy devices have been combined with imaging technology to better target a lesion in breast tissue. One such commercially available product is marketed under the trademark name MAMMOTOME™, by Ethicon Endo-Surgery, Inc. An embodiment of such a device is described in U.S. Pat. No. 5,526,822 issued to Burbank, et al., on Jun. 18, 1996, and is hereby incorporated herein by reference. Its handle receives mechanical and electrical power as well as vacuum assist from a remotely positioned control module that is spaced away from the high magnetic field of a Magnetic Resonance Imaging (MRI) machine.

[0004] As seen from that reference, the instrument is a type of image-guided, percutaneous coring, breast biopsy instrument. It is vacuum-assisted, and some of the steps for retrieving the tissue samples have been automated. The physician uses this device to capture "actively" (using the vacuum) the tissue prior to severing it from the body. This allows the sampling of tissues of varying hardness. In addition, a side opening aperture is used, avoiding having to thrust into a lesion, which may tend to push the mass away, cause a track metastasis, or cause a hematoma that, with residual contrast agent circulating therein, may mimic enhancement in a suspicious lesion. The side aperture may be rotated about a longitudinal axis of the probe, thereby allowing multiple tissue samples without having to otherwise reposition the probe. These features allow for substantial sampling of large lesions and complete removal of small ones.

[0005] Vacuum assisted core biopsy devices have been adapted to be safe and compatible with various imaging modalities, including Magnetic Resonance Imaging (MRI). In particular, portions of a biopsy system placed near the magnet core of an MRI machine need to be nonresponsive to the strong magnetic field to prevent becoming drawn toward the magnet core or to malfunction. Further, the MRI machine depends upon sensing extremely weak radio frequency (RF) signals emanated by tissue after being excited by a strong change in the magnetic field. Components placed in the RF shielded MRI suite need to avoid producing electromagnetic interference (EMI) and need to avoid having materials that would distort RF signals sufficient to create artifacts in the MRI scan data.

[0006] A successful approach has been to segregate motive power generation, graphical user interface, vacuum assist, and closed loop control in a control module that has typically been placed about 6 feet away from the magnet core to mitigate detrimental interaction with its strong magnetic field and/or sensitive radio frequency (RF) signal detection antennas. An intuitive graphical user interface (GUI) provides a range of preprogrammed functionality incorporated into a control module to efficiently use time in an MRI suite to take tissue samples.

[0007] As an example, in U.S. Pat. No. 6,752,768, the disclosure of which is hereby incorporated by reference in its entirety, a control button may be depressed to change a mode of operation of a core biopsy device with this mode displayed remotely on a display.

[0008] While a full function GUI has numerous clinical benefits, the clinician may find the control module inconveniently remote during hands-on portions of the procedure. In addition, some MRI machines have such increased sensitivity and/or increased magnet field strength that it is desirable to increase the distance of the control monitor (e.g., 30 feet) from the MRI machine. Further, even if the control monitor is sufficiently close, some clinicians prefer a simplified user interface to simplify training familiarity.

[0009] Consequently, a significant need exists for a biopsy system compatible for use in an MRI suite with biopsy controls with enhanced convenience and intuitiveness.

BRIEF SUMMARY OF THE INVENTION

[0010] The invention overcomes the above-noted and other deficiencies of the prior art by providing a handpiece of a magnetic resonance imaging (MRI) compatible core biopsy system that includes a graphical user interface that facilitates user control even with vacuum, power generation, and control processing components remotely positioned away from the MRI magnet and sensitive radio frequency (RF) receiving components. Thereby, a clinician may have the full functionality of vacuum assisted core biopsy systems yet not be inconvenienced by the distance from a remotely positioned control module.

[0011] loom These and other objects and advantages of the present invention shall be made apparent from the accompanying drawings and the description thereof.

BRIEF DESCRIPTION OF THE FIGURES

[0012] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodiments of the invention, and, together with the general description of the invention given above, and the detailed description of the embodiments given below, serve to explain the principles of the present invention.

[0013] FIG. **1** is a perspective disassembled view of a Magnetic Resonance Imaging (MRI) biopsy system including a handpiece ("biopsy device") having intuitive graphical controls consistent with aspects of the invention.

[0014] FIG. **2** is an isometric view of a lateral fence and pedestal of a localization fixture of the MRI biopsy system of FIG. **1**.

[0015] FIG. **3** is an isometric view of a guidance assembly mounted on a right primary targeting rail of FIG. **2**.

[0016] FIG. **4** is an exploded isometric view of the guidance assembly of FIG. **3** and the sleeve trocar and introducer obturator of FIG. **1**.

[0017] FIG. **5** is an isometric view of the introducer obturator inserted into the sleeve trocar of FIGS. **1** and **4**.

[0018] FIG. **6** is an aft right isometric view of the MRI biopsy device of FIG. **1** with a disposable probe assembly and keypad control disengaged from a reusable holster portion.

[0019] FIG. **7** is a fore left isometric view of the MRI biopsy device of FIG. **1** with the disposable probe assembly and keypad control disengaged from the reusable holster portion.

[0020] FIG. **8** is a fore left exploded isometric view of the reusable holster portion of FIG. **7**.

[0021] FIG. **9** is a top view of the disposable probe assembly of FIG. **7** with an upper cover removed to expose interior components of a carriage cavity.

[0022] FIG. **10** is a fore left exploded isometric view of the disposable probe assembly of FIG. **7**.

[0023] FIG. **11** is an aft left isometric view of the localization fixture and guidance assembly installed into a breast coil of FIG. **1**.

[0024] FIG. **12** is an aft isometric view of the MRI biopsy device of FIG. **7** into the guidance assembly of FIG. **11**.

[0025] FIG. **13** is a top detail view of a display portion of the MRI biopsy device of FIG. **7**.

[0026] FIG. **14** is an aft right isometric view of the MRI biopsy device, localization fixture and breast coil of FIG. **12** with insertion of a marker deploying instrument through a probe of the disposable probe assembly.

DETAILED DESCRIPTION OF THE INVENTION

[0027] An MRI biopsy device advantageously includes is partially disposable for sterility purposes with a reusable portion for economy. Inconvenience of mechanical, electrical, and pneumatical coupling to a remotely placed control portion, necessitated by a strong magnetic field and sensitive RF receiving components of an MRI machine, is mitigated. First, proximal detachable intuitive controls and displays on the MRI biopsy device give interactive control even after insertion into localizing and guiding structures. Second, binding of mechanical coupling to the MRI biopsy device is sensed prior to equipment damage or malfunction. Third, mechanical coupling is moved closer to engagement points between the MRI biopsy device and guiding structures to reduce torque loads, especially those transferred through its distal probe. Fourth, a single mechanical drive cable drives a fixed ratio transmission that translates and rotates a cutter of the distal probe to realize an effective fixed ratio translation/rotation sampling cut without the encumbrance of two mechanical drive cables.

[0028] Turning to the Drawings, wherein like numerals denote like components throughout the several views, in FIGS. **1-3**, a Magnetic Resonance Imaging (MRI) compatible biopsy system **10** has a control module **12** that typically is placed outside of a shielded room containing an MRI machine (not shown) or at least spaced away to mitigate detrimental interaction with its strong magnetic field and/or sensitive radio frequency (RF) signal detection antennas. As described in U.S. Pat. No. 6,752,768, which is hereby incorporated by reference in its entirety, a range of preprogrammed functionality is incorporated into the control module **12** to assist in taking these tissue samples. The control module **12** controls and powers an MRI biopsy device ("handpiece") **14** that is positioned and guided by a localization fixture **16** attached to a breast coil **18** that is placed upon a gantry (not shown) of the MRI machine.

[0029] A cable management spool **20** is placed upon a cable management attachment saddle **22** that projects from a side of the control module **12**. Wound upon the cable management spool **20** is a paired electrical cable **24** and mechanical cable **26** which are bundled into sheathed cable **27** for communicating control signals and cutter rotation/advancement motions respectively. In particular, electrical and mechanical cables **24**, **26** each have one end connected to respective electrical and mechanical ports **28**, **30** in the control module **12** and another end connected to a reusable holster portion **32** of the MRI biopsy device **14**. An MRI docking cup **34**, which may hold the holster portion **32** when not in use, is hooked to the control module **12** by a docking station mounting bracket **36**.

[0030] An interface lock box **38** mounted to a wall provides a tether **40** to a lockout port **42** on the control module **12**. The tether **40** is advantageously uniquely terminated and of short length to preclude inadvertent positioning of the control module **12** too close to the MRI machine. An in-line enclosure **44** may advantageously register the tether **40**, electrical cable **24** and mechanical cable **26** to their respective ports **42**, **28**, **30** on the control module **12**.

[0031] Vacuum assist is provided by a first vacuum line **46** that connects between the control module **12** and an outlet port **48** of a vacuum canister **50** that catches liquid and solid debris. A tubing kit **52** completes the pneumatic communication between the control module **12** and the MRI biopsy device **14**. In particular, a second vacuum line **54** is connected to an inlet port **56** of the vacuum canister **50**. The second vacuum line **54** divides into two vacuum lines **58**, **60** that are attached to the MRI biopsy device **14**. With the MRI biopsy device **14** installed in the holster portion **32**, the control module **12** performs a functional check. Saline is manually injected into biopsy device **14** to serve as a lubricant and to assist in achieving a vacuum seal. The control module **12** actuates a cutter mechanism (not shown) in the MRI biopsy device **14**, monitoring full travel. Binding in the mechanical cable **26** or within the biopsy device **14** is monitored with reference to motor force exerted to turn the mechanical cable **26** and/or an amount of twist in the mechanical cable **26** sensed in comparing rotary speed or position at each end of the mechanical cable **26**.

[0032] Just proximal to a display area **61** on the reusable holster portion **32**, a remote keypad **62**, which is detachable from the reusable holster portion **32**, communicates via the electrical cable **24** to the control module **12** to enhance clinician control of the MRI biopsy device **14**, especially when controls that would otherwise be on the MRI biopsy device **14** itself are not readily accessible after insertion into the localization fixture **16** and/or placement of the control module **12** is inconveniently remote (e.g., 30 feet away). An aft end thumbwheel **63** on the reusable holster portion **32** is also readily accessible after insertion to rotate the side from which a tissue sample is to be taken.

[0033] Left and right parallel upper guides **64**, **66** of a localization framework **68** are laterally adjustably received respectively within left and right parallel upper tracks **70**, **72** attached to an under side **74** and to each side of a selected breast aperture **76** formed in a patient support platform **78** of the breast coil **18**. A base **80** of the breast coil **18** is connected by centerline pillars **82** that are attached to the patient support platform **78** between the breast apertures **76**. Also, a pair of outer vertical support pillars **84**, **86** on each side spaced about a respective breast aperture **76** respectively define a lateral recess **88** within which the localization fixture **16** resides.

[0034] In FIGS. **1-2**, a selected breast is compressed along an inner (medial) side by a medial plate **90** downwardly

received into a medial three-sided frame **92** of the localization framework **68**. The breast is compressed from an outside (lateral) side of the breast by a lateral fence **94** downwardly received into a lateral three-sided frame **96** of the localization framework **68**, defining an X-Y plane. The X-axis is vertical (sagittal) with respect to a standing patient and corresponds to a left to right axis as viewed by a clinician facing the externally exposed portion of the localization fixture **16**.

[0035] Perpendicular to this X-Y plane extending toward the medial side of the breast is the Z-axis, which typically corresponds to the orientation and depth of insertion of a probe **98** of a disposable probe assembly **100** of the MRI biopsy device **14** or of a sleeve trocar **102** with inserted introducer obturator **104**. For clarity, the term Z-axis may be used interchangeably with "axis of penetration", although the latter may or may not be orthogonal to the spatial coordinates used to locate an insertion point on the patient. Versions of the localization fixture **16** described herein allow a nonorthogonal axis of penetration to the X-Y axis to a lesion at a convenient or clinically beneficial angle. An origin of the spatial coordinates may be imaging the dents imparted to the tissue by the lateral fence **94**. Alternatively, a disposable fiducial pointer **106** held by a fiducial holder **108** is filled with an MRI imagable material (e.g., KY jelly, saline, gadolinium) and sealed with a cap **110**.

[0036] The probe **98**, sleeve trocar **102** and fiducial pointer **106** are guided by the localization fixture **16**. With particular reference to FIG. **2**, a lateral fence supported pedestal **120** spatially positions left and right primary targeting rails **121**, **122** that in turn guide the fiducial pointer **106**, the sleeve/trocar **102**, or the probe **98** of the biopsy device **14** (FIG. **1**). The primary targeting rails **121**, **122** each include an attachment axle **124** that receives in either a left or right side axle hub **125** of a (Y-axis) height yoke **126** that is vertically adjustable upon a pedestal main body **128**, that in turn is laterally adjustable upon the lateral fence **94**. Alternatively, a breast coil may enable mounting the pedestal main body on the medial plate **90** for accessing medially. The pedestal main body **128** includes a proximal upright rectangular column **132** with a thinner wall **134** projecting from its distal side that flares laterally outward (defining left and right vertical rectangular slots **136**, **138**) as part of a bracket **140** with top and bottom hanger arms **144**, **146** that slide laterally respectively on a top track **148** and a proximally open lower track **150** formed in the lateral fence **94**. A lateral (X-axis) adjustment lever **151** may be raised to lift its distal end **149** out of engagement with a bottom track **147** formed in the lateral fence **94** as the lateral adjustment lever **151** is repositioned to the left or right to a desired location with reference to a lateral measurement guide **145**.

[0037] The height yoke **126** is a rectangular cuff interrupted in a mid-portion of a distal side to form locking left and right hands **152** respectively which ride vertically in the left and right vertical rectangular slots **136**, **138**. The locking left and right hands **152** have respective ridged proximal surfaces (not shown) that are selectively drawn proximally into locking engagement by a height locking lever **156** with a ridged surface **158** on a proximal side of each vertical rectangular slot **136**, **138**. Lifting the height locking lever **156** takes the height yoke **126** out of locking engagement to the pedestal main body **128** as the height yoke **126** is vertically repositioned. For height adjustment, the proximal top surface of the height yoke **126** serves as a sight **160** to read a height measurement scale **162** presented on a proximal surface of the height locking lever **156**.

[0038] The attachment axle **124** allows rotation so that an axis of penetration may include an upward or downward trajectory. In the illustrative version, proximal corners of the height yoke **126** include angle detents **164** (e.g., −15°, 0°,+15°) that are selectable by an angle lock lever **166**. The primary targeting rail **122** includes a distal detent **167** that serves as a home reference for the fiducial holder **108** (FIG. **1**).

[0039] In FIGS. **3**-**4**, a guidance assembly **200**, that may be attached to the lateral fence supported pedestal **120** of FIG. **2**, includes a cradle **202** whose upper lateral side **202***a* flares upwardly to engage a bottom channel **203** of the primary targeting rail **122**. A lower lateral side **202***b* flares horizontally to provide a holster guide track **204** that underlies the axis of penetration. To provide additional guidance to the MRI biopsy device **14** (FIG. **1**), a secondary targeting rail **206** includes a lateral channel **208** that is guided along a longitudinal guide tab **210** of the primary targeting rail **122**. When fully engaged thereon, a pawl **212** pivoting under urging of a pawl spring **214** about a vertical pawl pin **216** in a lateral window **218** proximally positioned in the secondary targeting rail **206** drops into a proximal detent **220** proximally positioned on the primary targeting rail **122**. The pawl spring **214** may maintain the pawl **212** in a neutral position that serves in both assembly and later removal of the secondary targeting rail **206** or comprises a pair of opposing pawl springs (not shown) for that purpose.

[0040] In FIGS. **4**-**5**, the sleeve trocar **102** includes a hollow shaft (or cannula) **223** that is proximally attached to a cylindrical hub **224** and has a lateral aperture **226** proximate to an open distal end **228**. The cylindrical hub **224** has an exteriorly presented thumbwheel **230** for rotating the lateral aperture **226**. The cylindrical hub **224** has an interior recess **232** that encompasses a duckbill seal **234**, wiper seal **236** and a seal retainer **238** to provide a fluid seal when the shaft **223** is empty and for sealing to the inserted introducer obturator **104**.

[0041] The introducer obturator **104** advantageously incorporates a number of components with corresponding features. A hollow shaft **242** includes a fluid lumen **244** that communicates between an imageable side notch **246** and a proximal port **248**. The hollow shaft **242** is longitudinally sized to extend when fully engaging a piercing tip **249** out of the distal end **228** of the sleeve trocar **102**. An obturator handle **250** encompasses the proximal port **248** and includes a locking feature **252**, which includes a visible angle indicator **254**, that engages the sleeve thumbwheel **230** to ensure that the imageable side notch **246** is registered to the lateral aperture **226** in the sleeve trocar **102**. An obturator seal cap **256** may be engaged proximally into the obturator handle **250** to close the fluid lumen **244**. The obturator seal cap **256** includes a locking or locating feature **258** that includes a visible angle indicator **259** that corresponds with the visible angle indicator **254** on the obturator thumbwheel cap **230**. The obturator seal cap **256** may be fashioned from either a rigid, soft, or elastomeric material.

[0042] Returning to FIGS. **3**, **4**, the sleeve trocar **102** is guided, during penetration of tissue, by a sleeve mount **260** having a sleeve hub **262** that receives the cylindrical hub **224** of the sleeve trocar **102**. The sleeve mount **260** has a lateral sleeve hub channel **264** that slides along top and bottom guide flanges **266**, **268** of the secondary targeting rail **206**, each having an aligned and recess ridged, ratcheting surface **270**

that interacts with a respective top and bottom ratcheting feature **272**, **274** on respective top and bottom rail lock rocker latches **276**, **278** that are engaged by respective top and bottom latch pins **280**, **282** in respective sides of the sleeve mount **260**. The ratcheting features **272**, **274** are proximally ramped such as to allow distal movement. Distal portions of each rail lock rocker latches **276**, **278** are biased away from the sleeve mount **260** by respective rail lock compression springs **284**, **286** to bias the ratcheting features **272**, **274** into contact with the ridges surfaces **270** of the guide flanges **266**, **268**. Simultaneous depression of the rail lock rocker latches **276**, **278** allow the sleeve mount **260** to be drawn proximally, withdrawing any sleeve trocar **102** supported therein, until the sleeve mount **260** reaches a proximal end of the secondary targeting rail **206**, whereupon the sleeve mount **260** rotates the pawl **212** clockwise (as viewed from the top) and is thus engaged to the secondary targeting rail **206** as the secondary targeting rail **206** is unlocked from the primary targeting rail **122**, causing removal therefrom with continued proximal movement.

[0043] Before mounting the secondary targeting rail **206** onto the primary targeting rail **122** in the first place, the sleeve mount **260** is advantageously adjustably positioned on the secondary targeting rail **206** to set a desired depth of penetration. In particular, a depth guide **290** is formed by a crescent-shaped depth indicator **292** having a lateral channel **296** shaped to engage the top and bottom guide flanges **266**, **268**. Forward ramped surfaces **298** on the top and bottom of the lateral channel **296** are positioned to engage the ridged ratcheting surfaces **270** on the secondary targeting rail **206**, allowing assembly by inserting the depth indicator **292** from a distal end of the secondary targeting rail **206**. Frictional engagement thereafter resists further proximal movement and strongly opposes any distal movement, especially from a depth lead screw **300** of the depth guide **290**, whose distal end **302** rotates within an outboard hole **304** in the depth indicator **292** and whose proximal end deflects laterally as a depth actuator lever **305** is used to rotate and longitudinally position the depth lead screw **300** therein. A mid portion of the depth lead screw **300** is received in a longitudinal through hole **306** formed in the sleeve mount **260** outboard of its lateral channel **208**. For coarse depth adjustment, outer lead threads **307** on the depth lead screw **300** selectively engage the sleeve mount **260** until top and bottom coarse adjust buttons **308**, **310** are inwardly depressed into the sleeve mount **260**, compressing respective top and bottom coarse adjust compression springs **312**, **314**. Each coarse adjust button **308**, **310** includes a respective vertically elongate aperture **316**, **318** whose inward surface presents a worm gear segment **320**, **322** to engage the outer lead threads **307** on the depth lead screw **300** when urged into engagement by relaxed coarse adjust compression screws **312**, **314**.

[0044] Returning to FIG. **3**, the thumbwheel **230** is depicted as engaged to the sleeve hug **262** of the sleeve mount **260** with other portions of the sleeve trocar **102** omitted. Application s consistent with the present invention may include a probe of an MRI biopsy device that includes a piercing tip or that otherwise is used without passing through a hollow shaft (cannula) **223**. As such, the thumbwheel with similar sealing members may be incorporated into the sleeve mount **260**.

[0045] In FIGS. **6-7**, the MRI biopsy device **14** has the disposable probe assembly **100** depicted detached from the reusable holster portion **32** and with the remote keypad **62** released from the reusable holster portion **32**. The sheathed cable **27** is joined to an underside of the reusable holster portion **32** distal to the aft end thumbwheel **63** to enhance balance and support of the reusable holster portion, which in turn may be engaged to the holster guide track **204** (FIG. **4**) by an I-beam shaped holster rail **324** whose upper surface **326** is engaged within a bottom channel **328** of a holster base plate **330**. A ridged member **331** upon the holster base plate **330** guides the disposable probe assembly **100** during engagement. A narrowed upper distal surface **332** of the holster rail **324** also engages downward gripping flanges **334** extending downward just proximal to a distal thumbwheel **336** of the disposable probe assembly **100**. An under slung shell **337** is fastened to the proximal undersurface portion of the holster base plate **330**.

[0046] The disposable probe assembly **100** also has an undersurface that backwardly slides into engagement with the reusable holster portion **32**. In particular, a narrowed proximal end **338** is formed into an upper cover **340** with a distal locking arm **342** separated from the upper cover **340** on each side except proximally to present an unlocking button **344** on an exposed surface **346** of the upper cover **340** that is depressed to disengage a locking surface **348** (FIG. **6**) from a distal lip **350** of a distally open receiving aperture **352** in the reusable holster portion **32** of the holster plate **330**.

[0047] A recessed deck **354** in an upper proximal surface of a proximal top cover **356** of the reusable holster portion **32** is shaped to receive the remote keypad **62**. A lower shell **358** mates to the proximal top cover **356**. The proximal top cover **356** also defines the upper portion of the receiving aperture **352**. The recessed deck **354** has a front guide hole **360** and a back locking aperture **362** registered to respectively receive a front tooth **363** and a flexing unlock tab **364** at an aft end of the remote keypad **62** to selectively engage and disengage the keypad **62** from the reusable holster portion **32**. The keypad **62** also includes a translation rocker button **366** that has a distal advance, a default neutral, and an aft retract command position. An aft button **368** may be programmed for mode functions such as saline flush.

[0048] With particular reference to FIG. **6**, the disposable probe assembly **100** has a plurality of interconnections presented on an aft docking end **370**. A rightward canted vacuum hose nib **372** is positioned to receive a vacuum conduit (not shown) that would be gripped by a friction clip **373** extending under and aft thereof to prevent inadvertent release. A right side slot **374** is distally open and formed between the holster base plate **330** and proximal top cover **356** to receive such a vacuum conduit as the disposable probe assembly **100** is engaged to the reusable holster portion **32**. A center splined driveshaft **375** engages the aft end thumbwheel **63** and communicates with the distal thumbwheel **336** to rotate a side aperture **376** in probe **98** to a desired side, as visually confirmed by an arrow indicator **378** on the distal thumbwheel **336**. A right splined driveshaft **380** effects cutter translation and a left splined driveshaft **382** effects cutter rotation.

[0049] The distal thumbwheel **336** and probe **98** are mounted to a cylindrical hub **384**, which is a distal portion of the lower shell **358** that extends beyond the mating with the upper cover **340**. A sample through hole **386** communicates through the cylindrical hub **384** for receiving a rotating and translating cutter tube **388** (FIG. **9**) that enters the probe **98** and for receiving tissue samples (not shown) deposited by a retracting cutter tube **388**. As the cutter tube **388** fully retracts into a carriage cavity **390** formed between the upper cover **340** and proximal portion of the lower shell **358**, a distally

extending tip **392** from a vacuum tube **394** encompassed by the cutter tube **388** dislodges the retracted tissue sample onto a sample retrieval platform **396**, which is a relieved area between the upper cover **340** and the cylindrical hub **384**.

[0050] In FIG. **8**, it should be appreciated that the sheathed cable **27** connects to the holster base plate **330** and communicates a single mechanical drive rotation to a fixed ratio transmission **398** mounted to the holster base plate **330** and electrically communicates with an encoder **400** coupled to the fixed ratio transmission **398** aft of the receiving aperture **352**. The sheathed cable **27** also communicates electrically with the display area **61** via a wire bundle (not shown) and with the keypad **62** via a cable assembly **402**, the latter including a strain relief bracket **404** that grips a keypad cable **406** and is fastened proximate to the sheathed cable **27**. The fixed ratio transmission **398** has a pass-through port **408** that receives a distal end the center splined driveshaft **375** (FIG. **6**) to rotatingly engage a proximally received beveled shaft **410** distally presented by the aft end thumbwheel **63** and sealed by an O-ring **412**. A right port **414** distally presented by the fixed ratio transmission **398** engages for rotation the right splined driveshaft **380** from the disposable probe assembly **100** for advancing and retracting ("translation") the cutter tube **388**. A left port **416** distally presented by the fixed ratio transmission **398** engages for rotation the left splined driveshaft **382** from the disposable probe assembly **100** for rotating the cutter tube **388** when a distal cutting edge of the cutter tube **388** slides past the side aperture **376** of the probe **98**.

[0051] In FIGS. **9-10**, the carriage cavity **390** of the disposable probe assembly **100** includes a cutter carriage **418** having a threaded longitudinal bore **420** that encompasses an elongate translation shaft **422** whose proximal termination is the right splined driveshaft **380** supported by an aft right cylindrical bearing **424** received in an aft wall **425** of the lower shell **358**. A race about the outer circumference of the cylindrical bearing **424** receives an O-ring **426**. A distal end **428** of the threaded translation shaft **422** rotates within a distal right cylindrical bearing **430** engaged to a forward wall **432** of the lower shell **358**. A race about the outer circumference of the cylindrical bearing **430** receives an O-ring **434**. A threaded central portion **436** of the elongate translation shaft **422** resides between an unthreaded distal over-run portion **438** and an unthreaded proximal over-run portion **440**, both sized to allow the threaded longitudinal bore **420** of the cutter carriage **418** to disengage from the threaded central portion **436**.

[0052] A distal compression spring **442** and a proximal compression spring **444** respectively reside on the unthreaded distal and proximal over-run portions **438**, **440** to urge the threaded longitudinal bore **420** of the cutter carriage **418** back into engagement with the threaded central portion **436** upon reversal of rotation of the elongate translation shaft **422**. In particular, the cutter carriage **418** includes a top longitudinal channel **446** that slidingly engages an undersurface of the upper cover **340** (not shown) and a bottom longitudinal guide **448** that engages a longitudinal track **450** on a top surface of the lower shell **358**. Thus rotationally constrained, rotation of the elongate translation shaft **422** causes corresponding longitudinal translation of the cutter carriage **418** with distal and aft pairs of gripping flanges **452**, **454** maintained laterally to the left to engage respectively distal and proximal races **456**, **458** formed on each side of a toothed portion **460** of a cutter spur gear **462**, which has a longitudinal bore for applying vacuum.

[0053] To that end, the vacuum hose nib **372** is attached to a mounting structure **464** that is gripped between the upper cover **340** and the lower shell **358** to present an orifice **466** within the carriage cavity **390** that is aligned with the longitudinal bore of the cutter gear **462** and that is in fluid communication with the vacuum hose nib **372**.

[0054] With particular reference to FIG. **10**, the proximal end of the vacuum tube **394** is received in the orifice **466**. A rectangular guide **467** supports the distally extending tip **392** of the vacuum tube **394** and is engaged between the upper cover **340** and the lower shell **358**. The cutter tube **388** encompasses and translates relative to the vacuum tube **394**. A seal cap **468** attached to a proximal end of the cutter gear **462** dynamically seals to the outer circumference of the vacuum tube **394** so that vacuum pressure supplied proximate to the distally extending tip **392** is not released within the carriage cavity **390**. The cutter tube **388** is advanced around the open distal end of the vacuum tube **394**, across the sample retrieval platform **396** to seal against a back seal **470** that substantially closes a proximal opening **472** into a sleeve union **474** that rotates within the cylindrical hub **384**. The sleeve union **474** has a distal end **476** engaged for rotation with the distal thumbwheel **336**. Distal and proximal O-rings **478**, **480** reside respectively within distal and proximal races **482**, **484** that straddle a lateral passage **486** of the sleeve union **474** to provide a degree of frictional resistance against inadvertent rotation and advantageously seal the lateral passage **486** for vacuum assistance to prolapse tissue and to retract samples. A noncircular opening **488** is centered in a distal face of the distal thumbwheel **336**. A proximal end of a probe tube **490** of the probe **98** extends through the noncircular opening **488** to receive a distal end of the cutter tube **388**. A lateral tube **492** attached along its length to the probe tube **490** communicates with the lateral passage **486** of the union sleeve **474**. The lateral tube **492** defines a lateral lumen that communicates with the a cutter lumen defined by the probe tube **490**/cutter tube **388** below the side aperture **376** through lumen holes **494** (FIG. **9**).

[0055] The center splined driveshaft **375** that is turned by the aft end thumbwheel **63** rotates in turn a shaft **496** whose keyed distal end **498** in turn is engaged to and rotates a pinion gear **500** that is in gear engagement to a proximal spur gear **502** that forms an outer proximal circumference of the sleeve union **474**. A cylindrical distal tip **504** of the keyed distal end **498** rotates within an axle hole (not shown) in the lower shell **358**. Rotation of the aft end thumbwheel **63** thus rotates the probe **98**.

[0056] A distal elbow pneumatic fitting **506** is supported in the lower shell **358** to have an upper end **508** communicating with the lateral passage **486** of the sleeve union **474** and an aft end **510** attached to a vent pneumatic conduit **512** supported by the lower shell **358**. The other end of the vent pneumatic conduit **512** is attached to a distal end **514** of a proximal elbow pneumatic fitting **516** whose lateral end **518** is open to atmosphere. Sizing of various components that vent atmospheric pressure through the lumen holes **494** from the lateral end **518** are such that a tissue sample may be withdrawn through the probe tube **490**. Yet a greater pneumatic draw of air through the vacuum hose nib **372** prior to severing a tissue sample results in a sufficient low pressure at the side aperture **376** to prolapse tissue for severing.

[0057] An elongate rotation shaft **520** proximally terminates in the left splined driveshaft **382** that is supported for rotation by a left aft cylindrical bearing **522** having a race

about an outer circumference that receives an O-ring **524** and is received in the aft wall **425** of the lower shell **358**. A distal end **526** of the elongate rotation shaft **520** is received for rotation in a left distal cylindrical bearing **528** having a race about an outer circumference that receives an O-ring **530** and that is received within the front wall **425** of the lower shell **358**. As the cutter carriage **418** advances to position the cutter tube **388** to slide past the side aperture **376**, the cutter spur gear **460** engages a spur gear portion **532** of the elongate rotation shaft **520**. Rotating the cutter tube **388** in proportion to an amount of rotation advantages secures an effective severing of tissue. Eliminating rotation when not severing advantageously enhances retraction of tissue sample retraction.

[0058] In use, in FIG. **11**, the localization fixture **16** has been installed into the breast coil **18**. The guidance assembly **200** has been preset for a desired insertion point, a desired axis of penetration, and a depth of penetration. After the sleeve trocar **102**/introducer obturator **104** have been inserted and imaged to confirm placement, the introducer obturator **104** is removed and the probe **98** of the biopsy device **14** is inserted, as depicted in FIG. **12**. The shape of the sleeve trocar **102** aligns the probe **98**, visually assisted by lining up the arrow indicator **378** on the distal thumbwheel **336** with the visible angle indicator on the thumbwheel **230** of the sleeve trocar **102**. The surgeon may effect operation of the biopsy device **14** by depressing the translation rocker button **366** and aft button **368** on the keypad **62** while referencing status information about the biopsy device **14** on the display area **61**. In FIG. **13**, the display area **61** advantageously includes a cutter position bar graph **534** having distal and proximal indications **536**, **538** that may be compared with how many light segments **540** have been illuminated to indicate progress of the cutter tube **388** relative to the side aperture **376**. The aft button **368** may be toggled to cycle the biopsy device **14** through three modes, indicated by a position LED indicator **542**, a sample LED indicator **544**, and a clear LED indicator **546** with a corresponding label that graphically depicts operation of the biopsy device in that mode. In particular, a position mode depiction **548** illustrates that the cutter tube **388** may be advanced and retracted, for instance, closing the side aperture **376** prior to insertion of the probe **98** into the sleeve trocar **102**. In a sample mode depiction **550**, vacuum assistance is implemented, drawing sufficient air through the cutter tube **388** to prolapse tissue into the open side aperture **376** that is maintained while translating the cutter tube **388**. In a clear mode depiction **552**, vacuum is maintained while fully retracting the cutter tube **388** to retract a tissue sample. In FIG. **14**, a marker device **548** is deployed through the sample through hole **386** in the cylindrical hub **388**.

[0059] It should be appreciated that any patent, publication, or other disclosure material, in whole or in part, that is said to be incorporated by reference herein is incorporated herein only to the extent that the incorporated material does not conflict with existing definitions, statements, or other disclosure material set forth in this disclosure. As such, and to the extent necessary, the disclosure as explicitly set forth herein supersedes any conflicting material incorporated herein by reference. Any material, or portion thereof, that is said to be incorporated by reference herein, but which conflicts with existing definitions, statements, or other disclosure material set forth herein, will only be incorporated to the extent that no conflict arises between that incorporated material and the existing disclosure material.

[0060] While the present invention has been illustrated by description of several embodiments and while the illustrative embodiments have been described in considerable detail, it is not the intention of the applicant to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications may readily appear to those skilled in the art.

[0061] For example, while closed loop feedback sensing of a component that is related to cutter tube position has various advantages, determination of cutter position may be achieved in other ways consistent with the present invention. For instance, loading on drive components may be sensed at either full advancement and/or full retraction which are used to calibrate an estimate cutter position based on duration of a translation command.

[0062] As another example, rather than discrete LED indicators and labeled depictions, applications consistent with aspects of the invention may include a graphical display (e.g., organic liquid crystal display) that is capable of interactive presentations of intuitive instrument status information. Alternatively or in addition, a touch screen capability may be incorporated to allow instrument control input as well as display.

[0063] For another example, applications consistent with aspects of the present invention may be used in conjunction with different diagnostic imaging modalities (e.g., ultrasonic, computed tomography (CT).

What is claimed is:

1. A biopsy device comprising:
- an outer cannula having a lateral tissue receiving aperture;
- an inner tubular cutter disposed for translation within the cannula;
- a sensor responsive to translation position of the inner tubular cutter;
- a graphical display attached proximally to the outer cannula operably configured to depict the translation position in response to the sensor.

2. The biopsy device of claim **1**, wherein the graphical display comprises a bar graph annotated with longitudinal extents of the lateral tissue receiving aperture relative to indicated translation position of the inner tubular cutter.

3. The biopsy device of claim **1**, further comprising a vacuum source communicating with the inner tubular cutter to prolapse tissue into the lateral tissue receiving aperture, the graphical display further operably configured to depict a mode of operation corresponding to the vacuum source.

4. The biopsy device of claim **3**, further comprising a mode control and control circuitry responsive to user activation of the mode control to toggle between a plurality of modes of operation, the graphical display including a plurality of indicators illuminated to correspond to a current mode of operation.

5. The biopsy device of claim **4**, further comprising a plurality of graphical depictions illustrating each of the plurality of modes of operation.

6. The biopsy device of claim **3**, further comprising a lateral lumen attached to the outer cannula and communicating distally to the lateral tissue receiving aperture and proximally to atmosphere.

7. The biopsy device of claim **1**, further comprising:
- a probe assembly portion containing the inner tubular cutter, a cutter carriage attached to the inner tubular cutter, and a translation shaft engaged for longitudinal translation to the cutter carriage; and

a holster assembly including a rotation member engageable to the translation shaft.

8. The biopsy device of claim **7**, wherein the probe assembly further comprises a cutter gear proximally attached to the inner tubular cutter, a rotation shaft having a spur gear portion positioned to engage the cutter gear to impart a rotation to the inner tubular cutter.

9. The biopsy device of claim **8**, wherein the holster further comprises a fixed ratio transmission having one rotation output engageable to the translation shaft and a another rotation output engageable to the rotation shaft.

10. The biopsy device of claim **9**, further comprising a remotely positioned cutter translation motor coupled via a mechanical drive cable attached to the holster.

11. The biopsy device of claim **10**, wherein the mechanical drive cable is attached to an undersurface of the holster to reduce torque loads at the outer cannula.

12. The biopsy device of claim **8**, wherein spur gear portion is longitudinally dimensioned to disengage from the cutter gear when all of the inner tubular cutter is retracted proximally to the lateral tissue receiving aperture.

13. The biopsy device of claim **1**, wherein the sensor comprises an encoder coupled to the inner tubular cutter.

14. A surgical biopsy system comprising:

a handpiece including an elongated, hollow cannula and a cutter rotatably and axially positionable relative to the hollow cannula, the hollow cannula having a lateral port for receiving the tissue sample into the hollow cannula;

a power source remotely positioned from the handpiece and operatively coupled via a mechanical drive cable to the cutter for rotating and translating the cutter;

a control unit operatively associated with the handpiece; and

a display attached to the handpiece and operatively configured with the control unit wherein the display provides a graphical display of an operational mode of the surgical biopsy system.

15. The surgical biopsy system of claim **14**, the handpiece further comprising at least one control button operable to select an operational mode of the surgical biopsy system.

16. The surgical biopsy system of claim **15**, wherein said at least one control button is positioned on a detachable keypad.

17. The surgical biopsy system of claim **14** wherein the handpiece is operably associated with a vacuum source.

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